#### GASTRODIA ELATA PEPTIDE HAND SANITIZING- hand sanitizer gel Tonghua Ren-Sheng-Yuan Biotechnology Co., Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# RenShengYuan, 70% Ethanol, Hand Sanitizing, Gel, 500mL

# Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic.

Gastrodia elata Blume peptide 5.5% v/v. Purpose: bactericidal against Candida albicans, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli.

# Purpose

Antiseptic, Hand Sanitizer

### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Used for hand sanitizing and surgical hand sanitizing.

# Warnings

- 1. External use of disinfection gel. Ban on oral. Keep this container out of the reach of children.
- 2. Avoid use with antagonistic drugs.
- 3. Caution for allergic people.
- 4. Keep away from the source of fire due to its inflammable.
- 5. Seal, and store in a cool and dry place.

# Do not use

- on children less than 2 months of age
- on open skin wounds
- in the eyes. in case of contact, rinse eyes thoroughly with water

When using this product keep out of eyes, ears, and mouth.

In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

# Directions

1.Sanitary hand disinfection: Take the right amount of this product on the palm, both hands rub each other to make uniform coating on each part for 1 minute.

2. Surgical hand antisepsis: After surgical hand washing, apply proper amount of this product evenly to the skin of the forearm and the lower third of the upper arm of both hands and rub for 3 to 5 minutes until

dry.

#### Other information

Seal, and store in a cool and dry place.

### **Inactive ingredients**

Water, Glycerine.

# Package Label - Principal Display Panel

[Product Name] <i>Gastrodia elata</i> Peptide Hand Sanitizing Gel		[Invention Patent No.] ZL201510534793.X [Quality Management System Cer] ISO 9001:2015
[Dosage Form] Gels [Main active ingredients and their contents] Gastrodia		[Specification] 500 ml per bottle
elata antimicrobial peptides, ethylalcohol (70%)	GASTRODIA ELATA	[Product Standard] GB27950-2011 Q/THRSY0056-2019
[Killing Microorganism Category] The bactericidal rate		【Hygiene License Number】吉卫消证字(2018)第0007号
against Candida albicans, Staphylococcus aureus,	PEPTIDE HAND	【Expiny Date】 12 months 【Research & Development Unit】 School of Life Sciences,
Pseudomonas aeruginosa, Escherichia coli is 99.99%.	SANITIZING GEL	Jilin University, China
[Serviceable Range] Used for hand sanitizing and		[Productive Enterprise] Tonghua Ren-Sheng-Yuan
surgical hand sanitizing. [Usage]		Biotechnology co., LTD
1.Sanitary hand disinfection: Take the right amount of		[Production Address] 1/1 Jingkai Ring Road, Tonghua city,
this product on the palm, both hands rub each other to	(W) PURE PLANT EXTRACTION	Jilin province, China
make uniform coating on each part for 1 minute.		[Postal Code] 134000
2. Surgical hand antisepsis: After surgical hand	(PH) WEAK ACID FORMULA	[Phone] +86-435-5110588
washing, apply proper amount of this product evenly to the skin of the forearm and the lower third of the upper arm of both hands and rub for 3 to 5 minutes until dry.		The batch number and productiondate of the product are shown on the bottle.
[Consideration]	W NO HORMONE	
1.External use of disinfection gel. Ban on oral. Keep this container out of the reach of children.	(+) EFFECTIVE STERILIZATION	
2.Avoid use with antagonistic drugs.		
3.Caution for allergic people.		
4.Keep away from the source of fire due to its inflammable.	Jilin University, China	
5.Seal, and store in a cool and dry place.	Research and development 500ml	6 971091 351088

# GASTRODIA ELATA PEPTIDE HAND SANITIZING

hand sanitizer gel

Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:75449-1001
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	Strength
GASTRODIA ELATA WHOLE (UNII: ZK2B063E7Q) (GASTRODIA ELATA WHOLE - UNII:ZK2B063E7Q)	GASTRODIA ELATA WHOLE	27.5 g in 500 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

#### **Inactive Ingredients**

**Ingredient** Name

GLYCERIN (UNII: PDC	C6A3C0OX)		
WATER (UNII: 059QF	OKOOR)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:75449-1001-1	500 mL in 1 BOTTLE; Type 0: Not a Combination Proc	luct 04/24/2020	
Marketing Inf	ormation		
Marketing Catego	ry Application Number or Monograph Citati	on Marketing Start Date	Marketing End Date
OTC monograph not fi	nal part333A	04/24/2020	

Labeler - Tonghua Ren-Sheng-Yuan Biotechnology Co., Ltd (554530164)

# **Registrant -** A03 Lab of BTS (548009541)

# Establishment

Name	Address	ID/FEI	Business Operations
Tonghua Ren-Sheng-Yuan Biotechnology Co., Ltd		554530164	label(75449-1001), manufacture(75449-1001)

Revised: 4/2020

Tonghua Ren-Sheng-Yuan Biotechnology Co., Ltd